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HENRY E. MILLSON JR. 675 GOLDEN HAWK DRIVE PRESCOTT, AZ 86301				SHEIKH, HUMERA N
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/053,299

Filing Date: January 17, 2002

Appellant(s): ZASLOFF ET AL.

Henry E. Millson, Jr.
Reg. No. 18,980
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 20, 2005 appealing from the Office action mailed June 03, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner, which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

An appeal brief was filed in this application on October 26, 2004. The Examiner reopened prosecution on 02/17/2005, in view of the appeal brief.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,607,711 B2	PEDERSEN	08-2003
6,770,306 B1	ZENG	08-2004

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

- **(A)** Claims 1-6, 8-16, 18, 25 and 41-44 are rejected under 35 U.S.C. §103(a) as being unpatentable over Pedersen (U.S. Patent No. 6,607,711).
- **(B)** Claims 1-6, 8-13, 18, 25, 31, 32, 34 and 41-44 are rejected under 35 U.S.C. §103(a) as being unpatentable over Pedersen (U.S. Patent No. 6,607,711).

*Note: The 35 U.S.C. §112, first paragraph rejection (Enablement and Written Description) has been withdrawn.

- **(A) - Claims 1-6, 8-16, 18, 25 and 41-44 are rejected under 35 U.S.C. §103(a)**
as being unpatentable over Pedersen (U.S. Patent No. 6,607,711).

Pedersen ('711) teaches a mouth hygienic composition and methods useful for the treatment of gingivitis, plaque formation and halitosis or bad breath wherein the composition comprises a metal ion and an essential amino acid, such as isoleucine (see reference column 1, lines 5-12); (col. 6, lines 17-25 and Abstract). The mouth hygiene composition also includes antimicrobial agents, such as cetyl pyridinium chloride; fluoride compounds such as sodium fluoride and sodium monofluorophosphate and saliva-inducing/sweetening agents such as xylitol (col. 7, lines 56-60); (col. 8, lines 35-46). The composition used for release in the oral cavity is suitably in the form of a lozenge, a troche, a chewing gum, toothpaste, a liquid mouth-rinsing composition, a sweet and a resoriblet (col. 8, lines 19-25).

Pedersen teaches that the mouth hygiene composition comprises chelates of a metal ion to preferably one, two or three amino acids (col. 5, lines 14-16). According to Pedersen, one aspect of his invention is largely due to the fact that plaque formation in the oral cavity is due to microbial growth and activity. By reacting with the sulfur-containing amino acids in the oral cavity, the metal ion moiety of the chelate significantly reduces the microbial growth potential which in turn is likely to lead to a reduced plaque formation (col. 8, lines 3-9).

The examples at columns 11-14 demonstrate various embodiments of the invention wherein zinc amino acid chelates were employed in combination with adjuvants, wherein the end results obtained indicated an effective reduction and inhibition of halitosis.

Applicants in claims 2-4 and 10-13 recite desired ranges of ‘microbial blocking quantities’ and desired ranges of ‘isoleucine’. Pedersen does not teach Applicant’s claimed

ranges. However, it is the position of the Examiner that, absent any showing of unexpected results accruable from the instant ranges, it would have been deemed obvious to one of ordinary skill in the art at the time the invention was made to determine suitable ranges or amounts of through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters within the art. Moreover, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). In the instant case, no criticality has been observed in the claimed concentration ranges since Applicants have not demonstrated any unexpected and/or unusual results, which accrue from the instantly claimed ranges. The prior art expressly desires and achieves therapeutically effective results for the treatment of gingivitis, halitosis and plaque formation through the combined use of amino acids, particularly isoleucine, antimicrobials, fluorides and sweetening/saliva-inducing agents (*i.e.* xylitol). Therefore, in view of the prior art teachings of Pedersen, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

This rejection is maintained and applied to newly added claims 41-44. Pedersen teach methods useful for the treatment of gingivitis, plaque formation and halitosis or bad breath wherein the composition comprises a metal ion and an essential amino acid, such as isoleucine (see reference column 1, lines 5-12); (col. 6, lines 17-25 and Abstract).

(10) Response to Argument

- (A) - Claims 1-6, 8-16, 18, 25 and 41-44 are rejected under 35 U.S.C. §103(a) as being unpatentable over Pedersen (U.S. Patent No. 6,607,711).

Appellant argued the following: “Pedersen’s compositions require the use of chelates of a metal ion, in which it is the metal ion that reduces microbial growth potential to combat halitosis. The amino acids used to form the chelates are reaction products only and do not exist as such in the chelate. The chelate of Pedersen is chemically unrelated to isoleucine and the metal chelates are cyclic compounds and function by an entirely different mechanism, i.e., metal ion reaction with sulfur-containing amino acids in the oral cavity. The use of a mixture of amino acids by Pedersen to form his metal chelates are reactants, not present as such in the cyclic chelate compounds”.

These arguments were not found to be persuasive. Pedersen (‘711), as delineated above, teaches a mouth hygienic composition and methods useful for the treatment of gingivitis, plaque formation and halitosis or bad breath wherein the composition comprises a metal ion and an essential amino acid, such as isoleucine (reference column 1, lines 5-12); (col. 6, lines 17-25 and Abstract). Appellant’s argument that “Pedersen’s compositions require the use of chelates of a metal ion, in which it is the metal ion that reduces microbial growth potential to combat halitosis” is not persuasive since Pedersen recognizes and teaches the incorporation of amino acids, such as isoleucine for use in treating conditions of the mouth, such as halitosis or bad breath and teaches that beneficial results are attained therewith. The instantly claimed language

allows for the presence of additional ingredients the permit an antimicrobial effect. Additionally, a review of the instant specification establishes that the compositions containing isoleucine can include one or more substances such as zinc ions (see specification, pg. 14, lines 3-5). Moreover, the Examiner notes that instant claim 11 also recites additional pharmacologically active substances that include metal ions, such as zinc ions. Thus, the chelates of metal ions taught by Pedersen would not be considered detrimental in the mouth hygienic composition, since clearly, as evidenced from Appellant's specification and claims, Appellant themselves desire the incorporation of metal ions, particularly zinc ions. Appellant's argument that "The amino acids used to form the chelates are reaction products only and do not exist as such in the chelate" and that "The use of a mixture of amino acids by Pedersen to form his metal chelates are reactants, not present as such in the cyclic chelate compounds" has been considered, but was not persuasive. Contrary to Appellant's argument that 'the amino acids do not exist in the chelate and are merely reactants', Examiner disagrees and asserts that the amino acids are present in the metal chelates. Pedersen teaches that amino acids that can be used in the preparation of metal amino acid chelates include isoleucine. The teaching of generic 'isoleucine' includes both (+) and (-) forms of isoleucine, thus meeting Appellant's claim limitations (see column 6, lines 17-25).

Appellant argued the following: "The following limitations are not taught or suggested by the Pedersen reference: Claim 1- (a) a method of blocking microbial adherence to a eukaryotic cell surface in a mammal by applying to said surface... (b) a pharmacologically acceptable composition consisting essentially of an amino acid component selected from the group

consisting of at least one of (an isoleucine isomer and active analogs of isoleucine)...(c) present in a microbial blocking quantity.”

Appellant’s arguments were not found persuasive. Pedersen teaches a mouth hygienic composition effective in treating halitosis, wherein the composition comprises a metal ion, and an amino acid, such as isoleucine (see Abstract; column 6, lines 17-25). The teaching of generic ‘isoleucine’ by Pedersen includes both (+) and (-) forms of isoleucine. Antimicrobial agents are also included in the composition, such as cetyl pyridinium chloride; fluoride compounds such as sodium fluoride and sodium monofluorophosphate and saliva-inducing/sweetening agents such as xylitol (col. 7, lines 56-60); (col. 8, lines 35-67). It is the position of the Examiner that since beneficial, antimicrobial effects are attained using Pedersen’s formulation, the amounts of amino acids present would also be a microbial blocking quantity as instantly claimed.

Appellant argued the following: “Claims 2-4 contain additional limitations relating to ranges of microbial blocking quantities. Pedersen does not disclose such ranges.”

Admittedly, while Pedersen does not disclose the ranges recited by Appellant, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). In the instant case, Applicants have not demonstrated any unexpected or superior results, attributable from the instantly claimed ranges. The prior art expressly desires and achieves therapeutically effective results for the treatment of gingivitis, halitosis and plaque formation through the combined use of amino acids, particularly

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isoleucine, antimicrobials, fluorides and sweetening/saliva-inducing agents (*i.e.* xylitol). Moreover, suitable or effective ranges could be determined by one of ordinary skill in the art through the use of routine or manipulative experimentation to obtain optimal results, as these are indeed variable parameters attainable within the art.

Appellant argued the following: "Claim 8 contains forms of the composition. Pedersen does not disclose such compositions for isoleucine."

The Examiner was not persuaded by this argument. Claim 8 recites the composition in 'the form of a dry powder, a paste, a solution, a gel, a tablet, a lozenge or a capsule'. Pedersen discloses that the composition for release in the oral cavity is suitably in the form of a lozenge, a troche, a chewing gum, toothpaste, a liquid mouth-rinsing composition, a sweet and a resoriblet (col. 8, lines 19-30). These composition forms read on the forms instantly recited in claim 8.

Appellant argued the following: "Claim 10 recites an (a) aqueous composition and (b) containing 0.01-50 µg/ml of the amino acid component. Pedersen does not disclose either of such limitations."

These arguments were not persuasive. Suitable forms of the amino acid composition taught by Pedersen include, for instance, a liquid mouth-rinsing composition (col. 8, lines 19-25). Pedersen teaches that the mouthwash formulation can be prepared by blending the composition or the chelate with suitable ingredients, such as aqueous ethanol, glycerin, sorbitol, surfactant, colorant, flavorant, antimicrobial agents and the like (col. 8, lines 61-67). Thus, Pedersen's composition includes an aqueous component. While the instantly claimed amounts of amino acid are not disclosed, effective amounts can be determined by the routine optimization process by the skilled artisan.

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Appellant argued the following: "Claim 11 recites (a) from about 0.001 to about 99% by weight; (b) of an isoleucine amino acid component; (c) at least one listed additional active substance. Pedersen does not disclose any of the above."

This argument was not deemed persuasive. Pedersen clearly teaches a composition for the treatment of halitosis comprising an amino acid component, particularly isoleucine (col. 6, lines 17-25). Amounts, as delineated above, absent any showing of unexpected results accruable from the instant amounts or ranges, can be determined through manipulative experimentation to obtain the best possible results. Pedersen, contrary to Appellants' assertion, does teach additional active substances, such as antimicrobial agents (*i.e.*, cetyl pyridinium chloride); fluoride compounds (*i.e.*, sodium fluoride & sodium monofluorophosphate) and saliva-inducing/sweetening agents (*i.e.*, xylitol) (col. 7, lines 56-60); (col. 8, lines 35-46).

Appellant argued the following: "Claims 12 and 13 recite additional weight limitations for isoleucine amino acids. No such disclosure by Pedersen."

These arguments were not found persuasive since Pedersen's amino acid composition amply provides for improved antimicrobial effects; thus demonstrating that efficient amounts of amino acid component are contained therewith.

Appellant argued the following: "Claim 18 recites (a) a cell surface blocking quantity; (b) of an isoleucine amino acid component; (c) in a toothpaste or gel form. No such disclosure by Pedersen."

Appellant's arguments were not persuasive, as Pedersen explicitly teaches an amino acid component formulated in various forms that include toothpaste, as instantly claimed (see col. 8, lines 19-60). Pedersen clearly teaches a toothpaste formulation and teaches how a toothpaste

formulation can be prepared. Claim 18 recites a ‘cell surface blocking quantity’, which is generally relative in terms of amounts. Pedersen’s amino acid-containing formulation provides sufficient antimicrobial effects and thus is considered to be contained in effective quantities.

Appellant argued the following: “Claim 42 recites (a) a quantity of amino acid component. Not disclosed by Pedersen.”

Appellant’s arguments were not persuasive, since as noted above, amounts, quantities and ranges can be determined by one of ordinary skill in the art through routine experimentation to obtain the best possible results, as these are considered variable parameters in the art. Appellants have not demonstrated any unexpected or superior results, which accrue from the amounts claimed. The prior art vividly recognizes and teaches a composition comprised of amino acids, such as isoleucine, to impart antimicrobial properties, useful in treating conditions of the mouth, namely halitosis.

Appellant argued the following: “Claim 44 recites infectious agent is bacteria. Not disclosed by Pedersen.”

Appellant’s argument has been considered, but was not persuasive. Pedersen recognizes the effect that amino acids provide on bacterial agents and addresses the concern of eliminating bacteria to overcome malodor (see column 1, lines 34-53).

Next, Appellant argued, “In the operating Examples, in Example 1, individuals having clinically evident low grade gingivitis were treated with isoleucine powder applied to the outer and inner gum margins of the upper and lower jaws. After 7 days of treatment, 80% of the cells were complete free of bacteria, while another 15% contained only 1-10 bacteria and only 5% had a continuous lawn of bacteria. This result compares to 90% of the cells containing a contiguous

lawn of bacteria prior to treatment with isoleucine. This result is surprising and unpredictable and clearly not taught or suggested by the Pedersen reference. In particular, this result was obtained using the amino acid isoleucine (and not a metal chelate where the metal ion is the effective halitosis agent). There is no disclosure in Pedersen leading one skilled in this art to use isoleucine absent a cyclic metal chelate for treatment of a gingivitis infection, particularly since Pedersen makes it clear that the metal ion in the chelate is the effective anti-halitosis agent.”

Appellant’s arguments have been considered, but were not persuasive. While Pedersen discloses that their formulation includes a metal ion chelate in combination with an amino acid (*i.e.*, isoleucine), the Examiner points out that Appellant’s themselves desire the use of a metal ion, particularly zinc ions, which are also disclosed in Pedersen. See Appellant’s claim 11, section (B) which recites that ‘the at least one pharmacologically active substance includes zinc ions’. It is the position of the Examiner that the presence of metal ion chelates in Pedersen does not promote any detrimental or adverse effects in the formulation. Moreover, the ‘consisting essentially of’ claim language recited by Appellants does not exclude the metal ions of Pedersen, since the metal ions are not deemed as detrimental components. The prior art provides for the use of the same ingredients, in the same field of endeavor, to treat the same problems (mouth hygienic conditions) to impart the same results as that desired by Appellants.

Appellant argued, “In Example 2 on pages 17-19, isoleucine was administered to treat infectious diarrhea. No medications were administered to the three patients having the infectious diarrhea. One individual was treated with oral isoleucine, six days after ingestion of the infectious agent, while the other two continued on restricted diets. A reduction of stool frequency was noted with the isoleucine patient within 12 hours of initiation of isoleucine

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therapy. This reduction continued until the third day when no stools were passed. By day 4, normal stool was passed and the diarrheal episode had passed. The two patients not treated with isoleucine experienced diarrhea for 11 days after ingestion of the infectious agent. This is an unexpected and surprising discovery in no way taught or suggested by the Pedersen reference."

The Examiner was not persuaded by this argument. The Examiner notes that the scope of the instant claims is not limited to the treatment of diarrhea by employing isoleucine. The instant claims are generic in terms of the desired conditions that can be treated using the amino acid, isoleucine. Since the prior art teaches the incorporation of the same amino acid, isoleucine, in similar formulations (*i.e.*, lozenge, troche, toothpaste, liquid mouth-rinsing composition, etc.), it is expected that the amino acid, isoleucine, would also be useful in treating an array of conditions, including diarrhea, to impart beneficial results. Thus, Appellant's arguments were not persuasive.

Appellant argued, "In Example 3, two women having irritable bowel syndrome (IBS) were treated with isoleucine in yogurt, where the yogurt itself had little effect on the IBS from previous experience. Within 2 days of isoleucine administration, bloating, urgency to defecate, and gaseousness had disappeared. Both individuals described their bowel function as normal for the first time in 20 years. The above results were unexpected and unobvious. The Pedersen patent contains no such disclosure."

These arguments were not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (*i.e.*, treating IBS) are not recited in the rejected claim(s). Although the

claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Appellant argued, "In Example 4, bacterial vaginosis was effectively treated in the vaginal cavity – in 2 days symptoms of vaginosis disappeared. The individual remained symptom free following cessation of isoleucine therapy."

Arguments were not persuasive, since, as delineated above, the scope of the instant claims are not limited to the treatment of vaginosis. The claims are silent with respect to particular or specific conditions to be treated using isoleucine. Moreover, Examiner notes that the claims are drawn towards 'a method of blocking microbial adherence to a eukaryotic cell' and are not drawn to a method of treating vaginosis. The prior art employs the same amino acid, used in a similar formulation and therefore, it is expected that similar results would be attained therewith.

- (B) - Claims 1-13, 18, 25, 31, 32, 34 and 41-44 are rejected under 35 U.S.C. §103(a) as being unpatentable over Zeng (U.S. Patent No. 6,770,306).

Zeng ('306) teaches a pharmaceutical composition and method for treating vaginitis, especially fungal vaginitis and reducing vaginal acidity consisting essentially of an effective amount of amino acids and physiologically acceptable salts of amino acids, wherein suitable amino acid compounds include isoleucine of L-type (see Abstract); (column 4, lines 11-26); (Claim 1).

The pharmaceutical composition can be in the form of lotion, drops, aerosol spray, suspension, emulsion, creams, tablets, suppository, gelate, ointments, microcapsules, sustained release dosage forms or any other acceptable vaginal local drug forms (see col. 4, lines 50-55) and Claim 5.

According to Zeng, the composition can also contain anti-fungal drugs of an effective amount, used for suppressing and killing fungi, and enhance the treatment effect of the composition of the invention for fungal vaginitis. The composition can also contain one or more pharmaceutically acceptable carriers (col. 3, lines 57-59); (col. 5, lines 32-39).

Zeng teaches that the amino acid total content is preferably is 30-350 mmol/L (col. 5, lines 1-5). The weight/volume content (W/V) of the composition refers to grams of the specific component in 100 milliliters of the composition. In liquid compositions, amino acids can be dissolved or suspended in one or more kinds of pharmaceutical carriers (col. 5, lines 46-52). The total dosage of amino acids as active components per day are preferred in amounts of 0.01-1.5 g, administered in one or more times (col. 6, lines 55-60).

The examples at columns 7-12 demonstrate compositions containing amino acids in various formulations and amounts. Example 1 at column 7 for instance, demonstrates the use of composite amino acids in an amount of 3.0g (glutamic acid, aspartic acid, isoleucine, methionine, phenylalanine, tyrosine, valine, leucine and praline of 2.36 mmol each), yeast extract powder, sodium bicarbonate and xanthan gum in a homogeneous mixture.

The amounts of isoleucine taught by the prior art are overlapping amounts, which read on the instant ranges and amounts claimed. Zeng does not expressly teach Applicant's ranges of 'microbial blocking quantities' recited in instant claims 2-4. However, absent any showing of

criticality accruable from the instant ranges, it would have been deemed obvious to one of ordinary skill in the art at the time the invention was made to determine suitable ranges or amounts of through the use of routine or manipulative experimentation to obtain the best possible results, as these are variable parameters within the art. Moreover, as delineated above, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected and/or unusual results, which accrue from the instantly claimed ranges. The prior art explicitly teaches formulations consisting essentially of amino acids, which include isoleucine, used for the effective treatment of vaginitis, especially fungal vaginitis. The prior art teaches the incorporation of the same active ingredient (isoleucine), employed in similar amounts, used in the same field of endeavor and to treat the same problems (fungal infections). Therefore, in view of the prior art teachings of Zeng, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

This rejection is maintained and applied to newly added claims 41-44. Zeng teaches methods for treating vaginitis, especially fungal vaginitis and reducing vaginal acidity consisting essentially of an effective amount of amino acids and physiologically acceptable salts of amino acids, wherein suitable amino acid compounds include isoleucine of L-type (see Abstract); (column 4, lines 11-26); (Claim 1).

(10) Response to Arguments

- **(B) - Claims 1-13, 18, 25, 31, 32, 34 and 41-44 are rejected under 35 U.S.C.**
§103(a) as being unpatentable over Zeng (U.S. Patent No. 6,770,306).

Appellant argued the following: “The Zeng reference is directed to a pharmaceutical composition which is effective in reducing vaginal acidity. The pharmaceutical composition for reducing vaginal acidity is characterized by containing one or more components such as amino acids, physiologically acceptable salts of amino acids, oligopeptides, polypeptides, optionally containing anti-fungal drugs of an effective amount; and one or more pharmaceutically acceptable carriers (col. 3, lines 42-59). In column 4, lines 11-21, it is stated that the ‘amino acids in the composition are formulations or combinations of many amino acids...’ and then lists 20 amino acids that can be used to form the ‘many amino acids’. Isoleucine is included as one of the many amino acids that can be present in the many amino acid mixtures. In column 4, lines 47-49, it is stated that ‘the composition containing only one or two sodium salts of amino acids can also partly realize the object of the invention.’, i.e., the use of only one or two sodium salts of amino acids cannot fully realize the object of the invention. This statement in effect directs one skilled in the art away from using only one or two amino acid salts in the invention. In fact, in the twenty operating Examples in columns 7-12, none of the compositions in which amino acids were used employed fewer than 8 amino acids.”

Appellant’s arguments have been fully considered, but were not persuasive. Admittedly, while isoleucine is included as one of the many amino acids in the formulations of Zeng, the instant claim language does not exclude the presence of additional ingredients that would not be

deemed detrimental. Zeng clearly teaches that fungal conditions, such as fungal vaginitis can be treated using amino acids, which include isoleucine and L-forms of isoleucine. Examiner notes that isoleucine is one amino acid listed amongst a group comprised of 20 amino acids. Isoleucine is also, however, one of the preferred amino acids for use in Zeng's formulation. See column 4, lines 17-21, wherein isoleucine is one of the preferred amino acids listed amongst a group comprised of only ten amino acids. Therefore, it is clear from the teachings of Zeng that isoleucine is a preferred and suitable amino acid for use in treating fungal infections (*i.e.*, fungal vaginitis). Appellant's argument that "Zeng's formulation leads one skilled in the art away from using only one or two amino acid salts in the invention" is not persuasive since one of ordinary skill in the art would be able to incorporate either one, two or multiple amino acids, based on the intended or desired result. Furthermore, the teaching of a multitude of amino acids by Zeng would not deter one of ordinary skill in the art from using their invention, since multiple amino acids would only be considered as aiding in attaining beneficial or improved results and would not be considered to impart adverse effects to the anti-fungal formulation. Appellant's argument that "In the twenty operating Examples in columns 7-12, none of the compositions in which amino acids were used employed fewer than 8 amino acids" was not persuasive since the teachings of Zeng are not limited to only the working examples illustrated therein. The teachings of the Zeng patent, as a whole, must be considered in determining patentability. Examiner also notes that whilst Zeng employs a plural number of amino acids in the examples, isoleucine is present in virtually all of the examples, which demonstrates that isoleucine is a pertinent amino acid for use in the formulation of Zeng (see columns 7-11). Also see claim 1 at column 14 for the teaching of isoleucine.

Appellant argued, "With respect to the treatment of fungal vaginitis, in column 14, lines 49-54, it is stated that 'even the composition of the invention containing no anti-fungal agents can cure some of the vaginal fungal infections'. This statement evidently refers to Experimental Example 1, where a patient with a fungal infection was treated with the composition of Example

1. The composition of Example 1 employed a mixture of 9 amino acids (including isoleucine) together with yeast extract powder, which contains 'abundant of amino acids, oligopeptide, and other protein hydrolytic products and vitamins' (col. 14, lines 34-36). There was no determination whether or not any particular component or components of this mixture possessed antifungal activity or whether it was simply the reduction in acidity that produced the antifungal activity".

The Examiner was not persuaded by this argument. Appellant is limiting the teachings of Zeng to one particular example. Appellant is also highlighting and placing emphasis on what the example does not suggest rather than what the example does suggest. Particular example 1 includes the use of isoleucine and therefore it is expected that antifungal activity, in part, would be achieved through employing the amino acid isoleucine.

Appellant argued, "In column 7, lines 37-42, it is stated that 'For the cases with typical fungal vaginitis, in particular for repeated and stubborn fungal vaginitis, the patient can be treated with the composition of this invention containing anti-fungal agents until the symptoms are alleviated.' Hence, cases of typical fungal vaginitis require the presence of anti-fungal agents for effective treatment."

Appellant's arguments were deemed unpersuasive. It is unclear to the Examiner as to how the presence of anti-fungal agents in Zeng would be deemed a negative component by Appellants, since Appellant's themselves desire the incorporation of additional pharmacologically active agents, such as anti-fungal agents. See claim 11, section (B), whereby Appellants claim "...at least one pharmacologically active substance selected from the group consisting of ...an antifungal agent...". Moreover, even aside from the inclusion of an antifungal agent by Appellants, Appellants also recite and claim a heap of supplemental active substances for use in their composition (see claim 11 in its entirety). Therefore, it is evident that Appellant's arguments are contradictory in nature, as Appellant themselves involve anti-fungal agents in their formulation.

The Examiner has interpreted the present claims as permitting mixtures of amino acids and refers to isoleucine as a preferred amino acid. As discussed above, this assumption is not accurate, since the present inventors have found that isoleucine, and only isoleucine and its stereoisomers and active analogs, have the unexpected benefits of blocking eukaryotic cell surfaces to prevent or at least significantly decrease microbial attachment to such cell surfaces. Independent claims 1, 11, 18 and 32 limits the amino acid component to isoleucine and its analogs. Also, component (B) in claim 11 excludes other amino acids as an additional pharmacologically active substance."

Appellant's arguments were not persuasive. The prior art amply teaches employing isoleucine in various forms such as L-isoleucine. The generic teaching of isoleucine would also include both (+) and (-) forms of isoleucine. Applicants have not demonstrated that the inclusion of additional components, such as the additional amino acids aside from isoleucine, would be

detrimental to the antimicrobial/antifungal composition. While multiple ingredients are included, it can only be reasoned that the multiple ingredients would be beneficial rather than adverse.

Appellant argued, “As noted by the Examiner, Zeng does not teach Appellant’s ranges of microbial blocking quantities for cell surfaces using only isoleucine as recited in claims 2-4. The argument concerning finding of suitable ranges is not relevant, since the use of amino acid mixtures, oligopeptides and polypeptides as neutralizing agents has nothing to do with using only isoleucine for the blocking of cell surfaces to block microbial adherence. The discovery of optimum or workable ranges by routine experimentation for blocking cell surfaces using only isoleucine presupposes that Zeng knew about such a concept, which clearly he did not.”

Appellant’s arguments were not persuasive. As stated above, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). In this instance, it is the position of the Examiner that Appellants have not demonstrated any unexpected or superior results, attributable from the instantly claimed ranges. The prior art expressly teaches a pharmaceutical composition for treating fungal conditions (*i.e.*, fungal vaginitis), whereby the composition is composed of amino acids, such as isoleucine, provided in therapeutically effective amounts. The prior art teaches a similar formulation, composed of similar ingredients, for use in the same field of endeavour to treat the same problems as that desired by Appellants.

Appellant argued, "Zeng's compositions containing amino acid mixtures are used to treat vaginitis resulting from highly acidic vaginas, i.e., as neutralizing agents. This disclosure has nothing to do with the method for blocking microbial adherence to eukaryotic cell surfaces (claims 1-10 and 41-44). Zeng does not teach any method for blocking cell surfaces using an isoleucine compound."

The Examiner was not persuaded by this argument. The formulation of Zeng is particularly used for the treatment of fungal vaginitis (see Abstract). Since Zeng's formulation provides for a method of treating fungal conditions, his formulation would also be considered a formulation that reduces or alleviates attachment of microbes, such as fungus. Zeng's formulation, contrary to Appellant's arguments, has much to do with the blockage of microbes.

Appellant argued, "The Zeng reference contains a number of limitations not taught or suggested by the Zeng reference, such as: Claim 1 – (a) a method of blocking microbial adherence to a eukaryotic cell surface; (b) by applying to said surface...an amino acid component selected from the group consisting of (isoleucine isomers and active analogs); (c) present in a microbial blocking quantity."

These arguments were not persuasive. Zeng, as discussed above, explicitly teaches a pharmaceutical composition and method for treating vaginitis, especially fungal vaginitis, consisting essentially of an effective amount of amino acids and physiologically acceptable salts of amino acids, wherein suitable amino acid compounds include isoleucine of L-type (see Abstract); (column 4, lines 11-26); (Claim 1). Zeng teaches that the amino acid total content is preferably is 30-350 mmol/L (col. 5, lines 1-5).

Appellant argued, “Claims 2-4 recite ranges of microbial blocking quantities.”

Appellant’s arguments were not persuasive. Absent evidence of unexpected or superior results that accrue from the instant amounts, it is the position of the Examiner that amounts as claimed can be attained through the normal optimization process by one of ordinary skill in the art.

Appellant argued, “Claim 11: amino acid component selected from the group consisting of (isoleucine isomers and active analogs)…”

Zeng clearly teaches the amino acid isoleucine and also L-forms of isoleucine. Both (+) and (-) forms would be included in the generic teaching of isoleucine.

Appellant argued, “Claims 12-13 recite quantities of the isoleucine present in the composition.”

Appellant’s arguments were not persuasive. Absent evidence of unexpected or superior results that accrue from the instant amounts, it is the position of the Examiner that suitable or effective amounts can be determined by one of ordinary skill in the art, as these are variable parameters in the art.

Appellant argued, “Claim 18 recites: (a) a toothpaste or gel...(b) amino acid component present in a cell surface blocking quantity...(c) which is an isoleucine isomer or active analog thereof.”

This argument was unpersuasive. The pharmaceutical composition taught by Zeng can be in the form of lotion, drops, aerosol spray, suspension, emulsion, creams, tablets, suppository, gelate, ointments, microcapsules, sustained release dosage forms or any other acceptable local drug forms (see col. 4, lines 50-55 and Claim 5).

Appellant argued, “Claim 31 recites: a composition in the form of a wound ointment or cream. Claim 32 recites: (a) a wound ointment or cream... (b) cell blocking quantity... (c) of an isoleucine isomer or active analog thereof. Claim 34 recites: skin ointment or cream.”

These arguments were unpersuasive, as Zeng explicitly teaches the various forms containing amino acid isoleucine. The various forms taught by Zeng include ointments and creams as instantly claimed by Appellant (see col. 4, lines 50-55 and Claim 5).

Finally, Appellant argued, “Claim 44 recites: a method for treatment of bacterial infection.”

This argument was not deemed persuasive. Zeng vividly addresses the concern for reducing or regulating bacteria. See for instance, column 2, lines 60-64, wherein Zeng states that patent (US 4,804,674) ‘does not indicate that amino acids, oligopeptide and polypeptide can regulate vaginal bacterial metabolism, nor does it indicate that acidity can be reduced by regulating vaginal bacterial metabolism. Also see column 3, lines 44-50, whereby Zeng states ‘amino acids, oligopeptides and polypeptides can change the metabolic process of bacteria and reduce acid production...’. Thus, Zeng’s formulation clearly provides for the effective treatment of bacterial conditions, as claimed by Appellant.

Based on the totality of teachings exhibited by the prior art, it is the position of the Examiner, that the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

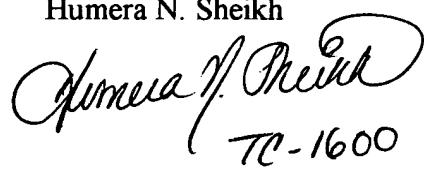
(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Humera N. Sheikh



TC-1600

hns

March 29, 2006

Conferees:

Thurman K. Page (SPE)

Sreeni Padmanabhan (SPE)

Humera N. Sheikh

THURMAN K. PAGE, M.A., J.D.
SUPERVISORY PATENT EXAMINER



SCREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

